To: All Healthcare Professionals
Re: Further Education on Propoxyphene Products
Date: February 14, 2011

Background for Notice

On November 19, 2010, the U.S. Food & Drug Administration recommended the withdrawal of propoxyphene products from the US market. The drug was pulled from the market in response to study data that demonstrated propoxyphene, even at recommended doses, caused heart rhythm abnormalities including prolonged PR interval, widened QRS complex, and prolonged QT interval[1]. If any patients have not been switched from propoxyphene, healthcare providers should work with patients to find an alternative option to help control their pain. A list of alternative medications is included in this notice along with information for your patients taking propoxyphene products.

Propoxyphene Drug Information

Propoxyphene is a schedule IV opioid approved to treat **mild to moderate** pain. It has been available as a single ingredient or combined with acetaminophen and marketed as generic and branded products (e.g. Darvon®, Darvocet®) The analgesic effect, onset, and duration of action of propoxyphene hydrochloride 65mg or propoxyphene napsylate 100mg is comparable to that of 650mg of acetaminophen[2]. Propoxyphene and its metabolite have an extended elimination half-life of 30-36 hours[3] that is even longer in the elderly. This contributes to an accumulation of medication and increased risk of adverse events. Abrupt discontinuation following prolonged use of any opioid, including propoxyphene, may lead to withdrawal symptoms.

Monitoring Patients after Therapy Change

- Educate patients on how a new pain medication works, any changes in the onset of effect, and what to expect.
- Schedule a follow-up visit to assess pain control and address patient questions. This is an important step to achieve therapeutic success and improve adherence to therapy.
- Specific monitoring is suggested for **NSAID use in older persons**. The American Geriatric Society recommends baseline identification and eradication of H. Pylori, baseline CBC with creatinine, with repeat creatinine three months after long-term therapy is initiated, and annual CBC with creatinine for duration of therapy [5].

Information for Patients

Propoxyphene is a medication used to help control **mild to moderate** pain. It is available as a single drug or in combination with acetaminophen (Tylenol®). Propoxyphene is marketed as generic and under brand names such as Darvon®, Darvocet®. A recent study led the Food & Drug Administration (FDA) to recommend the withdrawal of propoxyphene because taking the medicine, even at the recommended doses, could cause serious heart rhythm problems. There are many other medications you can use to help control your pain. If you are taking propoxyphene, you should work with your physician, pharmacist, or other healthcare provider to find the right medication for you.

If you have unused propoxyphene, safely dispose of the medication in household trash by:
1) Crush or dissolve the drug in water 2) Mix with something that will hide the medicine or make it unappealing, such as kitty litter or used coffee grounds 3) Place the mixture in a sealed plastic bag 4) Throw the container in your household trash. The DEA Drug Take Back Day is on Saturday, April 30th and is another option to get rid of unused propoxyphene. For more information go to: http://www.deadiversion.usdoj.gov/drug_disposal/takeback

Alternatives to Propoxyphene-Containing Medications [1,3,4,5]

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Medication	Dosing	Max. Dose	Patient Considerations
Non-Opioid Analgesics (first choice for **mild-moderate pain**)			
Acetaminophen *(Tylenol®)*	325-650mg every 4-6 hours or 1000mg 3-4 times/day	4000mg/day	-First-line for management of pain in the elderly -Use with caution if patient consumes more than 3 alcoholic beverages per day -Max dose if liver impaired is 2000mg/day
Meloxicam *(Mobic®)*	7.5mg daily	15mg/day	-Use NSAIDs cautiously in patients with diabetes, hypertension, renal insufficiency, and history of GI bleeding. -NSAIDs demonstrate a dose and time dependent adverse event profile including GI bleeding -Recommend separating concomitant cardioprotective low-dose aspirin administration due to heightened bleeding risk -The American Geriatric Society (AGS)[5] recommends against the first-line use of NSAIDs in geriatric patients -See the 2009 update of the AGS guidelines for more on the use of NSAIDs in older persons[5]
Nabumetone *(Relafen®)*	1000mg/day administered once or twice daily	2000mg/day	
Naproxen *(Aleve®)*	500mg initial, then 250mg every 6-8 hours as needed	1500mg/day	
Etodolac *(Lodine®)*	200-400mg every 6-8 hours as needed	1000mg/day	
Opioid Analgesics (use for **moderate-severe pain** not controlled by above)			
Hydrocodone/ Acetaminophen *(Lortab®; Vicodin®)*	5/325mg, 1 tablet every 4-6 hours as needed	4000mg/day acetaminophen	-Use with caution if patient consumes more than 3 alcoholic beverages per day. -Max dose if liver impaired is 2000mg/day of acetaminophen -Monitor for drowsiness, nausea and constipation
Acetaminophen/ Codeine #3 *(Tylenol #3)*	300/30mg, 1 tablet every 4-6 hours as needed	4000mg/day acetaminophen	
Tramadol *(Ultram®, Ultracet®)*	Starting dose at 25mg/day	400mg/day	-Monitor for opioid side effects of drowsiness, nausea, and constipation. -Risk of seizures if used in high doses or in predisposed patients

References:
[1]*Propoxyphene containing products*. Postmarket Drug Safety Information for Patients and Providers. www.fda.gov
[2]*Market withdrawal: Propoxyphene-containing products.* Kaiser Permanente Interoffice Memorandum. Nov 2010.
[3]*Lexicomp Online*. "Propoxyphene, naproxen." Retrieved January 14, 2011, from http://online.lexi.com
[4]Katz JD and Shah, T. Persistent pain the older adult: what should we do now in light of the 2009 American geriatrics society clinical practice guildeine? *Pol Arch Med Wewn*. 2009 Dec: 119 (12) 795-800.
[5]American Geriatrics Society Panel on Pharmacological Management of Persistent Pain in Older Persons. Pharmacological management of persistent pain in older persons. *J Am Geriatr Soc*. 2009; 57: 1331-1346.